UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
Western Division

CITY OF ROCKFORD on behalf of itself and all others similarly situated, Plaintiff, v. **MALLINCKRODT ARD INC.,** ***formerly known as*** **QUESTCOR PHARMACEUTICALS, INC.;** **MALLINCKRODT PLC;** ***and*** **UNITED BIOSOURCE CORPORATION,** Defendants.	**Civil Action No.: 3:17-cv-50107** Honorable Frederick J. Kapala Judge Presiding Magistrate Judge Iain D. Johnston

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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Mallinckrodt plc and Mallinckrodt ARD Inc. ("Mallinckrodt") submit this Memorandum in Support of their Motion to Dismiss the City of Rockford ("Plaintiff")'s Complaint.

INTRODUCTION

Mallinckrodt is a leading global specialty pharmaceutical company responsible for saving and improving the lives of millions of individuals worldwide. Its adrenocorticotropic hormone or ACTH drug, HP Acthar Gel ("Acthar"), is critical in the care and treatment of babies suffering from a rare condition of infantile spasms and instrumental in treating adults with conditions ranging from multiple sclerosis to arthritis. As set out herein, Plaintiff's Complaint fails to state any claim against Mallinckrodt and should be dismissed in its entirety.

LEGAL STANDARD

A motion to dismiss should be granted when a complaint fails to provide enough factual information to "state a claim to relief that is plausible on its face" and "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). Allegations that are "merely consistent with" a given cause of action are insufficient to satisfy the plausibility standard. *McCauley v. City of Chi.*, 671 F.3d 611, 616 (7th Cir. 2011). A plaintiff must "give enough details about the subject-matter of the case to present a story that holds together." *Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir. 2010).

"A plaintiff must allege that all elements of [the] claim are satisfied, but cannot survive a Rule 12(b)(6) motion to dismiss by alleging only legal conclusions." *Sullivan v. All Web Leads, Inc.*, No. 17C1307, 2017 WL 2378079, at *4 (N.D. Ill. June 1, 2017). Simple "threadbare recitals" of the elements of the claim, "supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A court is "neither bound by the plaintiff's legal characterization of the facts, nor required to ignore facts set forth in the complaint that

undermine the plaintiff's claim." *Bigalke v. Creditrust Corp.*, 162 F. Supp. 2d 996, 997 (N.D. Ill. 2001). When considering Plaintiff's Complaint in this light, dismissal is required here.

ARGUMENT

I. Plaintiff's Antitrust Claims Fail (Counts I and II).

Plaintiff brings two antitrust claims under the Sherman Act– one alleging monopolization under Section 2, and another alleging anticompetitive agreements in restraint of trade under Section 1. Both claims arise from Mallinckrodt's changed Acthar distribution system beginning in 2007 and the purchase of rights to a potentially competitive drug, Synacthen, in 2013. The gravamen of Plaintiff's antitrust claims is these actions "allowed Mallinckrodt to raise its prices" or use its "monopoly power to inflate the price of Acthar" or "preserve and extend its monopoly power and allow it to maintain and extend its high prices for Acthar." (Compl. ¶¶ 138-139, 157).

As a preliminary and decisive matter, the *Illinois Brick* doctrine categorically bars Plaintiff from bringing antitrust claims due to its status as an *indirect* purchaser since Plaintiff did not buy Acthar from either Mallinckrodt entity. Even if Plaintiff was properly positioned in the distribution chain for a Sherman Act claim, its grievance about high prices does not provide a cause of action under the antitrust laws, as set out below. "[T]he antitrust laws are not a price-control statute." *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995). Moreover, when considering the actions of an alleged monopolist, the law is clear that "[a] monopolist has no duty to reduce its prices or keep them low in order to help consumers." *Lerma v. Univision Commc'ns, Inc.*, 52 F. Supp. 2d 1011, 1020 (E.D. Wis. 1999). Finally, Plaintiff fails to make any non-conclusory allegations that Mallinckrodt's conduct had an adverse impact on competition. *See Banks v. Nat'l Collegiate Athletic Ass'n*, 977 F.2d 1081, 1093-94 (7th Cir. 1992).

Plaintiff's Complaint repeats antitrust buzzwords like "monopoly prices," "monopoly

power," and "anticompetitive conduct." However, "invocation of antitrust terms of art does not confer immunity from [dismissal]; to the contrary, these conclusory statements must be accompanied by supporting factual allegations." *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1110 (7th Cir. 1984). Plaintiff offers none, requiring dismissal of its antitrust claims.

A. The *Illinois Brick* Doctrine Bars Plaintiff's Antitrust Claims.

Section 4 of the Clayton Act permits injured parties to recover for antitrust violations, but recovery is firmly limited to *direct* purchasers following the landmark decision in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). In *Illinois Brick*, "[t]he Supreme Court intended to make a bright line rule for identifying the proper plaintiff when an antitrust violation occurs in a multi-tiered distribution system." *Del. Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1122 (9th Cir. 2008). Such a rule prevents duplicative recoveries and potential windfalls and avoids the complex calculations needed to determine the pass-on of overcharges through various levels of the distribution chain. *Illinois Brick*, 431 U.S. at 730-32. Accordingly, an indirect purchaser like Plaintiff is unable to recover under federal antitrust laws.

A person is an indirect purchaser when "[i]n the distribution chain, they are not the immediate buyers from the alleged antitrust violators." *Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 207 (1990). Here, Plaintiff does not and cannot allege it purchased Acthar directly from Mallinckrodt. Instead, Plaintiff makes bare allegations, fails to provide basic details like when purchases occurred or whom it purchased from, and offers inconsistent aggregate figures on its total Acthar expenditures. (Compl. ¶¶ 12, 21). At most, one can glean from the Complaint that Plaintiff's "purchases" were from a separate entity or specialty pharmacy several steps removed from Mallinckrodt: "Acthar is distributed through 'specialty pharmacies.'" (Compl. ¶ 3). Plaintiff actually holds itself out to be a downstream payor in the purchase of Acthar for city employees; Plaintiff is not a consumer of the drug.

Courts review the "mechanics of the transaction" when considering which party is the direct purchaser of pharmaceutical drugs *See, e.g.*, *Warren Gen. Hosp. v. Amgen, Inc.*, 643 F.3d 77, 88 (3rd Cir. 2011). *Warren General Hospital* is instructive here, as there a hospital was found to be an indirect drug purchaser under *Illinois Brick*. Specifically, in that case:

> The mechanics of the transactions [here] . . . reveal Warren General to be an indirect purchaser of Amgen's … drugs. First, when Warren General wants to purchase Amgen's . . . drugs it places its order through AmerisourceBergen. Accordingly, AmerisourceBergen charges Warren General for its order. Second, AmerisourceBergen maintains the right to set the price of the drugs it sells, and thus AmerisourceBergen's price is not necessarily the price it paid Amgen. Third, Warren General physically takes delivery of the shipment from AmerisourceBergen. Fourth, Warren General pays AmerisourceBergen directly; it transmits no funds to Amgen.

Id.

Even in a situation where "the manufacturers' increased prices had been passed in whole or part down the chain of distribution to the ultimate consumers," plaintiffs' federal antitrust claims were barred by *Illinois Brick* because they "had not purchased the drugs directly from the defendants, but rather from retailers." *In re Brand Name Prescription Drugs Antitrust Litig.*, 248 F.3d 668, 670 (7th Cir. 2001). Here, the connection between the initial sale of Acthar by the manufacturer and Plaintiff's "payments" is similarly attenuated. The most that can be inferred from Plaintiff's disparate allegations is that it could be no more than an indirect purchaser.

B. Plaintiff Fails to State Plausible Claims Under Section 1 or Section 2.

In any event, Plaintiff also fails to sufficiently allege the elements of its Section 1 and Section 2 claims. A Section 1 claim requires: "(1) a contract, combination, or conspiracy; (2) a resultant unreasonable restraint of trade in the relevant market; and (3) an accompanying injury." *Braman v. The CME Grp., Inc.*, 149 F. Supp. 3d 874, 895 (N.D. Ill. 2015) (citing *Denny's Marina, Inc. v. Renfro Prods., Inc.*, 8 F.3d 1217, 1220 (7th Cir. 1993)). *Twombly* requires "enough factual matter (taken as true) to suggest that an agreement [to restrain trade] was made."

550 U.S. at 556. "[A] conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality" and the facts pled must "raise a reasonable expectation that discovery will reveal evidence of illegal agreement." *Id.* at 556-557.

A Section 2 monopolization claim requires: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power." *In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, 767 F. Supp. 2d 880, 901 (N.D. Ill. 2011) (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). "The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). "[T]he willful acquisition or maintenance" of monopoly power must be "distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident" to state a viable claim. *Endsley v. City of Chi.*, 230 F.3d 276, 282 (7th Cir. 2000) (citing *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 481 (1992)).[1] That is because "Section 2 forbids not the intentional pursuit of monopoly power but the employment of *unjustifiable means* to gain that power." *Id.* at 282 (emphasis added). "Simply possessing monopoly power and charging monopoly prices does not violate § 2." *Pacific Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 447-48 (2009).

Plaintiff's Section 1 and 2 claims both center on Mallinckrodt's use of an exclusive distribution arrangement and its purchasing the rights to Synacthen – but these unremarkable business activities do not plausibly state a claim under the Sherman Act.

1. Exclusive Distribution Arrangement.

Here, Plaintiff claims the Acthar distribution arrangement is an unreasonable restraint of

[1] Plaintiff does not allege Mallinckrodt *obtained* its monopoly through improper means, but rather monopoly power was improperly *maintained*. (Compl. ¶ 138).

trade under Section 1 and illegal maintenance of a monopoly under Section 2. Plaintiff alleges that in 2007, Mallinckrodt "contracted with Curascript [sic] to be its exclusive specialty pharmacy distributor of Acthar throughout the country." (Compl. ¶ 51). It also alleges that Mallinckrodt "engages UBC as its exclusive agent to coordinate all aspects of the drug prescription/authorization, distribution and payment." (Compl. ¶ 45).

Plaintiff frequently levies general allegations about the Acthar distribution process and pairs them with conclusory statements regarding monopolistic conduct, but offers no allegations explaining how the exclusive distribution arrangement is anticompetitive. Instead, Plaintiff just makes bare allegations like the following (conclusory language is italicized):

- "As discussed below, in 2007, Questcor changed its distribution of Acthar, vertically integrating its sales and distribution through one exclusive distributor, Curascript [sic]. *This was the beginning of Mallinckrodt's monopolistic conduct and unlawful scheme to inflate the prices of Acthar.*" (Compl. ¶ 4).

- "But in July 2007, Questcor embarked on a new strategy and business model: to limit distribution to one specialty pharmacy distributor (Curascript [sic]) *to enhance its monopoly power and to increase the price of Acthar more than tenfold*[.]" (Compl. ¶ 5).

- "[I]n 2007, Mallinckrodt *leveraged and enhanced its monopoly power* by limiting the distribution of its sole specialty drug to just one specialty pharmacy distributor, and employing an exclusive agent, UBC, to coordinate all aspects of its distribution and sales of its product[.]" (Compl. ¶138).

This manner of pleading is insufficient. *See Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) ("Because [the plaintiff] has failed to allege facts which, if true, would establish that the two licensing agreements at issue are unreasonable restraints on trade that caused antitrust injury to consumers, its § 1 and § 2 claims fail as a matter of law").

It is well-accepted that "[t]he benefits of exclusive dealing are many." Phillip E. Areeda & Herbert J. Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶1810 (2013). As Judge Posner has noted, "[w]hat

is more common than exclusive dealing?" *Methodist Health Services Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410 (7th Cir. 2017). Generally, "[s]uppliers should have the discretion to structure their own distribution." *Lerma*, 52 F. Supp. 2d at 1020. However, there are two paradigm situations where exclusive distribution agreements can have "adverse economic consequences:" (1) "allowing one supplier of goods or services unreasonably to deprive other suppliers of a market for their goods" or (2) "allowing one buyer of goods unreasonably to deprive other buyers of a needed source of supply." *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 45 (1984) (O'Connor, J., concurring), abrogated on other grounds by *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006). Plaintiff has alleged neither of these consequences and offers only bare allegations that an exclusive distributor led to higher prices. Plaintiff does not describe how the arrangement supposedly allows Mallinckrodt to raise its price any more than it otherwise could given its alleged status as a monopolist. *See E&L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006) (exclusive distribution arrangement "provides no monopolistic benefit to [defendant] that it does not already enjoy"). A monopolist is able to control its prices regardless of how many distributors (if any) it chooses to use. Plaintiff is also silent about the pre-2007 distribution system and how it differed materially from the current system. In reality, the Acthar distribution arrangement has no bearing on monopolist status or the ability to set monopoly prices.

Because exclusive distribution arrangements are not unusual and only rarely can be anticompetitive, a Section 1 claimant must plead an anticompetitive effect of the agreement. *See Car Carriers*, 745 F.2d at 1107; *see also Brown v. Visa U.S.A., Inc.*, 674 F. Supp. 249, 252 (N.D. Ill. 1987). Specifically, "the plaintiff must allege, not only an injury to himself, but an injury to the market as well." *Car Carriers*, 745 F.2d at 1107; *see also Bunker Ramo Corp. v. United Bus.*

Forms, Inc., 713 F.2d 1272, 1285 (7th Cir. 1983) (dismissing Section 1 claim where plaintiff had "not alleged any anticompetitive effect arising from the defendants' conduct, nor [was the court] able to infer such an effect from the facts alleged" because "[t]he closest [the plaintiff] comes to implicating any effect on competition is a bare allegation that it was charged an 'artificially high, non-competitive price'").

Plaintiff offers no non-conclusory allegations that the Acthar distribution arrangement harms or restricts competition, particularly interbrand competition. *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 890 (2007) ("[The] primary purpose of the antitrust laws is to protect [interbrand] competition"); *see also Bunker Ramo*, 713 F.2d at 1283. Plaintiff only alleges its "injuries consist of paying higher prices to purchase Acthar than it would have paid absent Mallinckrodt's unlawful conduct." (Compl. ¶¶ 144, 152). Pleading one's own payment of "high, non-competitive" prices is not enough. *Bunker Ramo*, 713 F.2d at 1285. Courts should be "unwilling to construe pleadings so liberally as to imply an anticompetitive effect or harm to competition where there is not even a bare allegation of such an effect and the alleged facts do not support one." *Id.* Plaintiff's failure to allege anticompetitive harm requires dismissal.

A monopolization claim under Section 2 also requires more than an allegation of high prices; there must be an adverse impact on competition. Plaintiff's monopolization claim fails since exclusive distribution is a valid business strategy that has no impact on market power or competition; merely alleging an exclusive distribution arrangement is insufficient to state a plausible monopolization claim. *See Filter Queen of the Virginias, Inc. v. Health-Mor, Inc.*, No. 89 C 5511, 1990 WL 36824, at *3–4 (N.D. Ill. Mar. 20, 1990). Plaintiff fails to allege any plausible theory as to why having a sole distributor is anticompetitive or contributes to

improperly maintaining monopoly power.

In *Health-Mor*, plaintiffs—defendant's former distributors—claimed a changed distribution system was "an attempt to monopolize and a conspiracy between Health–Mor and its distributors in restraint of trade" and their complaint was essentially a "general attack on Health–Mor's distribution system of exclusive distributorship territories in a relevant market for expensive vacuum cleaners." *Id.* at * 3. When considering dismissal, the court was "somewhat confused by the monopolization and attempted monopolization claims, since plaintiffs do not tell us how the vertical distribution restraints (and we are talking about vertical rather than horizontal restraints) lead to monopolization or drive competitors from the marketplace." *Id.* Ultimately, the Court found "[i]t is not an antitrust violation to change distributors" and dismissed the claim. *Id.* at *4. *Health-Mor* applies with equal force here, as Plaintiff fails to explain how a vertical distribution restraint (i.e., the alleged exclusive distribution arrangement) injures competition.

2. Purchase of Synacthen.

Plaintiff also alleges Mallinckrodt's purchase of the rights to Synacthen violated antitrust laws since, at that time, Synacthen "was a synthetic version of Acthar and the only potentially competitive product in the market." (Compl. ¶ 7). Specifically, Plaintiff refers to a contract between Questcor and its "competitor," Novartis, dated June 11, 2013, through which, Plaintiff alleges, "Questcor [Mallinckrodt] gained the exclusive rights to develop, market, and sell Synacthen." (Compl. ¶ 84).[2] Plaintiff appears to surmise that if *another* company had bought Synacthen, it would have impacted Acthar pricing or it would have been a substitute product that

[2] The bulk of Plaintiff's Synacthen allegations are direct quotations or references to an earlier Federal Trade Commission ("FTC") complaint and consent decree, which are improper. Mallinckrodt has filed contemporaneously herewith a motion to strike such allegations as immaterial and prejudicial in accordance with Section 5(a) of Clayton Act and Rule 12(f). *See Damon Corp. v. Geheb*, No. 80 C 1500, 1982 WL 1927, at *1 (N.D. Ill. Nov. 23, 1982) (striking improper references to FTC matter). Without these improper allegations regarding the FTC proceedings, the Complaint is completely devoid of any substantive allegations plausibly showing the purchase of Synacthen to be anticompetitive.

Plaintiff would have purchased at a lower price. Essentially, Plaintiff contends it would have paid less but-for Mallinckrodt's acquisition of Synacthen, and that constitutes an antitrust claim.

Mallinckrodt vigorously rejects the notion that the acquisition of Synacthen was an antitrust violation, but even if true, Plaintiff could still not state a claim. An antitrust violation alone is insufficient to pursue a damages claim. *See J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 562 (1981). A plaintiff must also show it was injured as a result of the violation, often referred to as "injury-in-fact" or "fact of damage." *Story Parchment Co. v. Patterson Parchment Paper Co.*, 282 U.S. 555, 562 (1931). Plaintiff must allege how the market would have been different "but-for" the supposed wrongful conduct and show how its injury would have been avoided in that "but-for" market. *E.g., Fishman v. Estate of Wirtz*, 807 F.2d 520, 550 (7th Cir. 1986) (showing fact of damage requires "quantifying the difference between what actually happened and what would have happened in a hypothetical free market").

Plaintiff must sufficiently allege that "but-for" the acquisition of Synacthen, prices for Acthar would have been lower. *See, e.g., Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 259-63 (1946). Plaintiff makes no such allegations, nor could it because of the rigorous FDA drug approval process Plaintiff itself acknowledges. (Compl. ¶¶ 62-64). Plaintiff alleges only that Synacthen was "potentially" competitive with Acthar when Mallinckrodt acquired it in 2013. (Compl. ¶¶ 67-68). Any supposed anticompetitive effect from this acquisition, then, could not have occurred until after 2013. Plaintiff fails to allege when it paid for Acthar, but its only claim of "injury-in-fact" (and that must be inferred) is that: (i) Synacthen would have been available in the U.S. market at the time it paid for Acthar; (ii) Acthar would have been cheaper; and/or (iii) Plaintiff would have purchased Synacthen instead of Acthar at a lower price. This theory is analogous to the entry of a generic drug that reduces the price for a drug previously on patent.

Plaintiff alleges no facts plausibly showing that, at the time Plaintiff paid for Acthar, the "potentially" competitive Synacthen: (i) could have gone through additional development; (ii) obtained necessary government approvals; (iii) would have been in the market; and (iv) would have been priced lower than Acthar. To the contrary, Plaintiff acknowledges the FDA approval process is lengthy and complex and there was substantial "uncertainty [whether] Synacthen, a preclinical drug, would be approved by the FDA." (Compl. ¶¶ 64, 67). Plaintiff's claim of injury is wholly speculative. And given that the antitrust laws require a "reasonable degree of certainty" that "injury-in-fact" occurred, the Complaint is entirely inadequate in this regard. *See, e.g., Dominguez v. UAL Corp.*, 666 F.3d 1359, 1361-62 (D.C. Cir. 2012) (injury too speculative to satisfy "injury-in-fact" requirement and not supported by "specific facts").

3. High Prices are More Plausibly Caused by the Orphan Drug Status.

In evaluating a purported antitrust claim, "the court is not required to don blinders and to ignore commercial reality." *Car Carriers*, 745 F.2d at 1110. "Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns*, 540 U.S. at 411. "To survive a motion to dismiss, a claim must make economic and factual sense." *Lerma*, 52 F. Supp. 2d at 1025. Neither of Plaintiff's claims make sense or set out plausible antitrust violations.

Relevant here, the Orphan Drug Act was enacted in 1983 (Public Law No. 97-414) to incentivize pharmaceutical companies to develop drugs for rare diseases and conditions. *See* 21 U.S.C. § 360aa-ff (2012). One such incentive is codified as "orphan drug exclusivity," 21 U.S.C. § 360bb(a)(2)(A-B), which provides a seven-year exclusivity period where "[t]he disease or condition for which the drug is intended affects fewer than 200,000 people in the United States" or "there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States[.]" 21 C.F.R. 316.20 *et seq.*

Given the rarity of infantile spasms and the uniqueness of Acthar, the FDA designated it as an "Orphan Drug" on May 31, 2003, and provided marketing approval on October 15, 2010. (*See* Compl. ¶ 36). This status brings a seven-year period of exclusivity, during which time the FDA will not approve any other version of the drug to treat infantile spasms. Plaintiff itself concedes that a "distinguishing feature of specialty pharmaceuticals like Acthar" is "high prices." (Compl. ¶ 3). The more plausible explanation for the Acthar pricing about which Plaintiff complains is that it is the natural result of a lawful monopoly for an orphan drug and reflects the price consumers were willing to pay.

II. Plaintiff's Allegations Do Not State a Claim for Any RICO Violation (Counts III-V).

Courts should use "common sense" when analyzing RICO claims. *Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 782 (7th Cir. 1994). The statute intends to prevent instances "in which a person bent on criminal activity seizes control of a previously legitimate firm and uses the firm's resources, contacts, facilities and appearance of legitimacy to perpetrate more, and less easily discovered, criminal acts than he could do in his own person[.]" *Fitzgerald v. Chrysler Corp.*, 116 F.3d 225, 227 (7th Cir. 1997). Here, however, Plaintiff seeks to effectively criminalize Mallinckrodt's pricing and unremarkable distribution network. This bears no resemblance to the organized criminal conduct Congress sought to eradicate with RICO.

The thrust of Plaintiff's RICO claims is that Questcor, and then Mallinckrodt, charged high prices for Acthar and used a single distributor. But just as these allegations do not support any antitrust claims, realizing profit and commanding "high" prices is not a RICO offense. The alleged purpose of Mallinckrodt's actions—"distributing, marketing, selling, purchasing, and administering Acthar to plaintiff [sic] and the Class, and deriving substantial profits from these activities"—belies any claim of unlawful conduct. (Compl. ¶ 157). And while Plaintiff claims using a single distributor was a scheme to inflate prices, its own allegations support an obvious

alternative, and benign, explanation: "vertically integrating its sales and distribution through one exclusive distributor" for a limited-production, specialty, "orphan" drug was efficient, economical, and streamlined. (Compl. ¶¶ 3, 70). Plaintiff's RICO claims wholly lack merit.

A. Plaintiff Has Failed to State a Claim Under 1962(c) (Count III).

A Section 1962(c) RICO claim requires allegations of facts showing: (1) conduct; (2) of an enterprise; (3) through a pattern; (4) of racketeering activity. 18 U.S.C. § 1962(c). A plaintiff cannot simply allege the elements in "boilerplate fashion," but "must allege sufficient facts to support each element." *Goren v. New Vision Int'l, Inc.*, 156 F.3d 721, 727 (7th Cir. 1998).

1. Plaintiff's Allegations Improperly Lump Together Defendants.

A plaintiff cannot state a RICO claim by, as here, "lumping together" defendants. *Id.* at 730. Plaintiff defines "Mallinckrodt" as both Mallinckrodt ARD and its parent company, Mallinckrodt plc, and fails to articulate specific conduct attributable to each party. (Compl. ¶¶ 1, 22, 25). Thus, when Plaintiff attributes conduct to "Mallinckrodt," its faulty naming convention results in allegations being levied against two completely separate companies. Plaintiff asserts Mallinckrodt ARD (which Plaintiff defines as "Questcor") is responsible for the manufacture, distribution and sale of Acthar, but makes no such allegation against Mallinckrodt plc – nor is there a basis for one. (Compl. ¶ 23). Plaintiff names Mallinckrodt plc in this action owing solely to its status as Mallinckrodt ARD's parent company. (Compl. ¶¶ 1, 22, 24). This is patently improper and ineffective to state a claim against Mallinckrodt plc. "It is clear that liability under RICO is limited to persons who have 'personally committed' at least two predicate acts of racketeering. There is no vicarious liability under RICO." *Emery v. Am. Gen. Fin., Inc.*, 938 F. Supp. 495, 499 (N.D. Ill. 1996) (rejecting RICO claim against parent company where plaintiff merely alleged existence of parent-subsidiary relationship). Further, "[a] parent company will be a proper RICO defendant only if it participated in the wrongful conduct of its subsidiary." *All-*

Tone Commc'ns, Inc. v. American Info. Tech., No. 89 C 7883, 1991 WL 166532, at *2 (N.D. Ill. Aug. 26, 1991) (plaintiff failed to adequately allege RICO claim against parent corporation) (*citing D & S Auto Parts, Inc. v. Schwartz*, 838 F.2d 964, 966-67 (7th Cir. 1988)).

Plaintiff also often defines "Mallinckrodt" and UBC collectively as "Defendants" and levies general, collective allegations against all Defendants instead of particularized ones. (Compl. ¶¶ 160-172, 178). Plaintiff does not allege which Defendants were engaged in what predicate acts or the nature of their participation. This pleading defect requires dismissal. *Freedom Mortg. Corp. v. Burnham Mortg., Inc.*, 720 F. Supp. 2d 978, 995 (N.D. Ill. 2010).

2. Plaintiff Has Not Adequately Alleged the Existence of an Enterprise.

Plaintiff alleges "an association-in-fact enterprise … consisting of Mallinckrodt, UBC, and CuraScript, including their directors, employees, and agents." (Compl. ¶ 156). But a corporation plus its agents is not an "enterprise." *Chrysler*, 116 F.3d at 228; *Baker v. IBP, Inc.*, 357 F.3d 685, 691 (7th Cir. 2004). RICO does not apply "to a free-standing corporation … merely because [it] does business through agents, as virtually every manufacturer does[.]" *Chrysler*, 116 F.3d at 227; *Rowe v. Bankers Life & Cas. Co.*, No. 09-cv-491, 2010 WL 3699928, *6 (N.D. Ill. Sept. 13, 2010); *Rocha v. FedEx Corp.*, 15 F. Supp. 3d 796, 807 (N.D. Ill. 2014). Plaintiff repeatedly alleges UBC and CuraScript are agents of Mallinckrodt, which is patently defective. (Compl. ¶¶ 27, 43, 45-48, 130-31, 138, 156, 158). So too is any claim that the two Mallinckrodt defendants could be a purported RICO enterprise. *Chrysler*, 116 F.3d at 228.

Nor does Plaintiff otherwise allege facts showing an enterprise. The Supreme Court has taken a liberal view of what suffices, but the bounds are not limitless. *United Food & Commercial Unions & Employers Midwest Health Benefits Fund v. Walgreens Co.*, 719 F.3d 849, 853-54 (7th Cir. 2013) (*Boyle* still requires the enterprise have an ascertainable structure and a "person … distinct from the RICO enterprise"); *Myers v. Seung Heun Lee*, No. 1:10-cv-

131, 2010 U.S. Dist. LEXIS 99707, at *18 (E.D. Va. Sept. 21, 2010) (enterprise activities "must be distinguishable from the normal day to day activities"). Plaintiff claims the RICO enterprise is "manifested in the ASAP program." (Compl. ¶¶ 156-59). But ASAP (Acthar Support and Access Program) is just an acronym for the system by which, as Plaintiff alleges, "drug prescription/authorization, distribution, and payment" are coordinated to "ensur[e] efficient seamless service" for Acthar patients. (Compl. ¶¶ 23, 44-45). This is not distinct from Defendants' day-to-day activities, nor is the supposed enterprise distinct from the conduct at issue: employing a single distributor to deliver Acthar.

3. Plaintiff's Allegations Reveal No Conduct of a RICO Enterprise.

Plaintiff's allegations are devoid of facts showing the Defendants "conducted or participated in the conduct of the enterprise's affairs," as opposed to simply furthering their own commercial interests. *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001) (citations omitted). In *Walgreens*, the Seventh Circuit rejected the employee benefit plan's RICO claim where Walgreens and a drug maker, Par, allegedly overcharged for prescriptions. 719 F.3d at 850. The companies "regularly communicated" and there were "communications … in which Par proposed [a] drug-switching program and Walgreens agreed to implement it" *Id.* at 854-55. "But nothing in the complaint reveals how one might infer that these communications or actions were undertaken on behalf of the enterprise as opposed to on behalf of Walgreens and Par in their individual capacities, to advance their individual self-interests." *Id.* at 855. "Instead, the activities the complaint describes are entirely consistent with Walgreens and Par each going about its own business, with Par manufacturing generic drugs and marketing its products to pharmacies, and Walgreens purchasing drugs and filling prescriptions." *Id.*

A defendant must "participate in the operation or management of the enterprise itself" and "have some part in directing those affairs." *Reves v. Ernst & Young*, 507 U.S. 170, 179, 183

(1993). A complaint must plead facts plausibly alleging a degree of cooperation and coordination "that fell outside the bounds of the parties' normal commercial relationships." *Nesbitt v. Regas*, No. 13-C-8245, 2015 WL 1331291, at *8 (N.D. Ill. March 20, 2015); *In re Insurance Brokerage Antitrust Litig.*, 618 F.3d 300, 378 (3rd Cir. 2010). As the Seventh Circuit noted in *Walgreens*:

> while it is true that Walgreens does not make drugs and Par does not fill prescriptions, and that the two companies must therefore "cooperate" in order for drugs to reach consumers, *such cooperation describes virtually every prescription pharmaceutical distribution chain. The allegations in the complaint do not indicate how the cooperation in this case exceeded that inherent in every commercial transaction between a drug manufacturer and pharmacy*, and without such an indication, we cannot find a basis for inferring [they] were conducting the enterprise's affairs.

719 F.3d at 856 (emphasis added).

Plaintiff fails to specifically identify *any* communications, much less facts revealing conduct of an enterprise's affairs as opposed to cooperation furthering each party's own interests. Generalized claims about "a common communication network" by which Defendants and CuraScript "shared and continue to share information on a regular basis" are of no moment. (Compl. ¶ 159). And while Plaintiff contends "Mallinckrodt's conduct in sending e-mails, faxes and other communications to UBC to direct the distribution and sale of Acthar through ASAP" reveals a price inflation scheme, these actions are entirely consistent with each party simply advancing its own interests to sell and distribute Acthar and support Acthar patients.

Unable to articulate how each Defendant operated or managed the enterprise (since none existed), Plaintiff resorts to generalized, conclusory allegations that all "Defendants" have exerted control over the enterprise, have associations with it, and conduct and participate in its affairs. (Compl. ¶¶ 160-61). These naked boilerplate allegations do not pass muster. *Goren*, 156 F.3d at 727. Plaintiff also does not, and cannot, claim Defendants "involved themselves in the affairs of the other" or "that profits were siphoned off." *Walgreens*, 719 F.3d at 855.

4. Plaintiff Fails to Allege Any Predicate Acts with Requisite Specificity.

Plaintiff utterly fails to allege *any* predicate racketeering acts. Plaintiff claims Defendants engaged in anticompetitive conduct and charged "inflated" prices for Acthar. High prices do not constitute an antitrust violation and, in any event, a "violation of antitrust law is not a predicate act under RICO." *Jennings v. Emry*, 910 F.2d 1434, 1437 (7th Cir. 1990).

Plaintiff alleges the parties' fraudulent scheme consisted of "confining patients to an exclusive distribution network, such that they could drastically inflate the prices charged for Acthar." (Compl. ¶ 162). "A necessary element of a scheme to defraud is the making of a false statement or material misrepresentation, or the concealment of a material fact." *Williams v. Aztar Indiana Gaming Corp.*, 351 F.3d 294, 299 (7th Cir. 2003). Plaintiff alleges no facts whatsoever – much less with heightened Rule 9(b) specificity – supporting a plausible inference that any party engaged in fraud in connection with the distribution system or pricing for Acthar. Fraud does not arise simply because a party believes a company charges too much.

Plaintiff's mail and wire fraud claims, which must also be pleaded with heightened specificity, are woefully deficient. *Slaney v. The Int'l Amateur Athletic Fed'n*, 244 F.3d 580, 597-99 (7th Cir. 2001) ("plaintiff must, at a minimum, describe the two predicate acts of fraud with some specificity and state the time, place, and content of the alleged false representations, the method by which the misrepresentations were communicated, and the identities of the parties to those misrepresentations"); *Emery v. Am. Gen. Fin., Inc.*, 134 F.3d 1321, 1323 (7th Cir. 1998).

Plaintiff fails to allege a *single* instance of wire or mail fraud, claiming instead the parties have a "common communication network" and "share information on a regular basis." (Compl. ¶ 159). Plaintiff claims such unspecified communications "typically" occurred "by use of the wires and mails" and that "Mallinckrodt, UBC, and Curascript [sic] all agree to charge inflated prices for Acthar[,]" but does not, and cannot, specify the time, place, content, and parties to *any*

such communications. *Goren*, 156 F.3d at 729. Plaintiff fails to describe any details whatsoever. Plaintiff also critically fails to explain how any communication (i) contained a misrepresentation, (ii) was made to, and (iii) reasonably relied upon by Plaintiff. There are none.

Plaintiff's rampant speculation that unspecified communications "likely involved hundreds, if not thousands, of separate instances of the use of the" mail or wires or that "[e]ach of these fraudulent mailing and interstate wire transitions" was racketeering activity is inadequate. (Compl. ¶ 161). "The Seventh Circuit … does not look favorably on relying on many instances of mail and wire fraud to form a pattern." *Vicom*, 20 F.3d at 781. As Plaintiff has failed to sufficiently describe a single instance of mail or wire fraud, *a priori* it fails to allege a pattern of racketeering activity.

5. Plaintiff's Allegations Are Insufficient to Establish RICO Injury or Causation.

Plaintiff's alleged RICO injury is "economic injuries in the form of overcharges." (Compl. ¶ 127). "A plaintiff alleging damages in out-of-pocket losses must allege these damages as a quantifiable, 'clear and definite' monetary amount." *Southern Illinois Laborers' and Employers Health and Welfare Fund v. Pfizer Inc.*, No. 08-cv-5175, 2009 WL 3151807, at *4 (S.D.N.Y. Sep. 30, 2009) (citing *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 227 (2nd Cir. 2008). "Courts disfavor damages estimates that require speculation or that are based upon factors other than the defendant's misrepresentations." *Id.* Moreover, only a "concrete financial loss" constitutes a cognizable injury under RICO. *District 1199P Health and Welfare Plan v. Janssen, L.P.*, No. 06-3044 (FLW), 2008 WL 5413105, at *7 (D.N.J. Dec. 23, 2008) (TPP-plaintiff's claim that it overpaid for prescription drugs did not constitute cognizable RICO injury). Even if Plaintiff's vague "overcharges" claim could support a RICO injury, which it cannot, Plaintiff cannot plausibly show any "overcharges" were caused "by reason of a

violation" of RICO. (Compl. ¶ 127).

A plaintiff must show the RICO violation was both the "but-for" and proximate cause of injury. *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992). Plaintiff posits that but-for (i) the use of a single distributor, (ii) the Synacthen acquisition, and (iii) Synacthen not coming to market, Plaintiff would have paid "lower" Acthar payments. But any overcharges were not "by reason of a violation" of RICO, since none of these are violations. Regardless, Plaintiff's allegations reveal its causation theory is impermissibly attenuated. Plaintiff does not allege facts showing how using multiple distributors would have impacted prices. (Compl. ¶¶ 159-60, 162). Nor has Plaintiff plausibly alleged alternative drugs could have been available in the market to impact Acthar pricing at all, let alone by the time Plaintiff paid for Acthar. Plaintiff's allegations reinforce that Acthar is the only drug FDA-approved for therapeutic use in the U.S., there are no substitutes, and it was uncertain whether Synacthen could obtain FDA approval and clear the "high barriers to entry" for the ACTH market. (Compl. ¶¶ 55, 63-64, 67).

Nor do Plaintiff's allegations plausibly demonstrate proximate cause. "When a court evaluates a RICO claim for proximate causation, the central question … is whether the alleged violation led directly to the plaintiff's injuries." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006). Courts have recognized that claims by third party payors (TPPs) seeking to recoup "losses" occasioned by prescription reimbursements pose proximate causation issues. *E.g., Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 192 F. Supp. 3d 963, 968 (N.D. Ill. 2016) (collecting cases) (dismissing TPP plaintiffs' putative class action for lack of causation). After reviewing numerous TPP proximate causation cases, the *Hillman* court concluded "the distinguishing characteristic [is] whether the drug manufacturer directly made misrepresentations to the TPP because otherwise intervening factors – such as a physician's independent medical

judgment or a patient's decision making – interrupt the chain of causation." *Id.* at 970; *see also In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 159 F. Supp. 3d 898, 913-14 (N.D. Ill. 2016) (determining factor is whether defendants made misrepresentations directly to TPP plaintiffs).

Similarly, in *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prod. Liab. Litig.*, Nos. 3:09-cv-20071, 3:09-md-02100, 2010 WL 3119499, at *5 (S.D. Ill. Aug. 5, 2010), the health benefit fund-plaintiffs could not establish causation to pursue RICO claims related to improper promotion of FDA-approved drugs. "[A] majority of courts considering the issue have concluded that the injury for which third party payors seek reimbursement is too remote and speculative to maintain a RICO claim." *Id.* at *6 (collecting cases). Ultimately, the purported injury of paying too much for the drug was too attenuated since "multiple steps separate[d] the alleged wrongful conduct … and the alleged injuries," with "the causal link necessarily involv[ing] the decision making process of the patient, the prescribing physician, and the third party payor." *Id.* at *7. Here, Plaintiff does not and cannot allege Mallinckrodt made any representations to Plaintiff, much less *misrepresentations that caused Plaintiff to decide to pay for Acthar*.[3] *In re Yasmin*, 2010 WL 3119499, at *7; *UFCS Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2nd Cir. 2010). This lack of causation requires dismissal.

Plaintiff's own allegations also reveal some of the contingent steps that must occur before it actually reimburses for Acthar, and which courts have said interrupted causation. A physician must determine Acthar is "medically necessary." (Compl. ¶ 47; "Acthar Start Form" at Exhibit A, p. 1). The patient or physician "contacts Mallinckrodt for a prescription" and then fills out the

[3] The observation in *Hillman* that plaintiff "do[es] not mention anything about their prescription reimbursement process in the … class action complaint or how they came to pay for [the drug], only conclusorily alleging that they have paid or reimbursed such prescriptions…." resonates here. 192 F. Supp. 3d at 970-71. Plaintiff offers no detail about how and when it decides to cover the cost of Acthar.

Acthar Start Form. (Compl. ¶¶ 46-47, Ex. A). The patient authorizes, in Plaintiff's words, "'Mallinckrodt and its agents' to do a number of things in relation to the prescription of Acthar," including sharing the patient's health information and providing various services, "including reimbursement coverage and support." *Id.* A "preliminary assessment of benefit verification" is conducted to "confirm the patient's insurance coverage or other source of payment." (Compl. ¶¶ 46, 49). As noted on the physician certification, "insurance verification is ultimately the responsibility of the provider and *third-party reimbursement is affected by a variety of factors*." (Compl. Ex. A) (emphasis added). The Complaint does not describe the remaining steps in the process, but common sense dictates they include, at least: (i) the insurer or other payment source confirming they approve and/or will pay for Acthar; (ii) Acthar being ordered, delivered, and paid for; and (iii) Plaintiff at some point receiving and paying a reimbursement demand. And, of course, at some (or each) point in the process, the patient must decide they want to proceed with the Acthar treatment. This is far too remote to state a claim.

6. Plaintiff Cannot Use RICO to Privately Enforce the FDCA.

To the extent Plaintiff bases any RICO claims on the Acthar label, this impermissibly seeks to privately enforce FDA regulations where the Federal Food, Drug and Cosmetic Act ("FDCA") contains no private cause of action.[4] 21 U.S.C. § 337(a). Issues concerning the accuracy of drug labels (which Plaintiff notes are submitted to and approved by the FDA) fall squarely within the province of the FDA. (Compl. ¶ 97). Once a new drug is approved by the FDA, the manufacturer must distribute the drug with its FDA-approved labeling, and failure to do so can give rise to criminal liability for distributing a misbranded drug. *See* 21 U.S.C. §§ 331(c), 333(a), 352(a), (c). A drug is misbranded under the FDCA if, among other things, its

[4] Plaintiff's claims regarding the Acthar label appear to be offered as part of its purported ICFA claim, not RICO. (Compl. ¶¶ 96, 120). Those assertions are addressed in Section III(D) *infra*.

labeling is false or misleading in any particular." 21 U.S.C. § 352(a).

Courts regularly dismiss efforts to privately litigate violations of the FDCA. *E.g. In re: Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) (claims about drug labeling and advertisements "largely constitute[d] an attempt to shoehorn allegations that Defendants have engaged in [misbranding] in violation of the FDCA into RICO and state consumer fraud [claims]"); *Sandoz Pharm. Corp., v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3rd Cir. 1990) (Lanham Act claim that drug's label misleadingly and inaccurately identified "active" ingredients properly dismissed because FDA was better suited to interpret and enforce its regulations).

B. Plaintiff Has Failed to State a Claim Under 1962(a) (Count IV).

Plaintiff's 1962(a) RICO investment injury claim requires facts showing the Defendants (1) received income from a pattern of racketeering activity; (2) used or invested that income in the operation of an enterprise; and (3) caused injury by the use or investment of the racketeering income in an enterprise. *Rao v. BP Products N. Am., Inc.*, 589 F.3d 389, 399 (7th Cir. 2009). The harm from the investment activity must be distinct from the 1962(c) harm. *Grove Fresh Distrib., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 716-17 (N.D. Ill. 1989).

Plaintiff offers only boilerplate allegations that racketeering "income was used to acquire, establish, and/or operate the ASAP Enterprise" and conflates its 1962(a) claim with the same racketeering activity and injury alleged in its 1962(c) claim: overpayment for Acthar. (Compl. ¶¶ 164, 167, 170). And Plaintiff's bare allegation that its injury "was distinct from the injury caused by the pattern of racketeering activity" is devoid of factual support. (Compl. ¶ 171).

C. Plaintiff's 1962(d) Conspiracy Claim Similarly Fails (Count V).

Plaintiff's RICO conspiracy claim fails for all of the reasons above. When a Section 1962(c) claim fails, a Section 1962(d) claim premised upon the same facts also fails. *Walgreens*,

719 F.3d at 387; *Goren*, 156 F.3d at 732; *In re Honey Trans. Lit.*, 87 F. Supp. 3d 885, 866 (N.D. Ill. 2005). Plaintiff's conspiracy claim fails for another reason: Plaintiff has made no nonconclusory allegations evidencing an illicit agreement. A RICO conspiracy requires showing that: "(1) the defendant agreed to maintain an interest in or control of an enterprise or to participate in the affairs of an enterprise through a pattern of racketeering activity, and (2) the defendant further agreed that someone would commit at least two predicate acts to accomplish those goals." *Slaney*, 244 F.3d at 600. "[T]he touchstone of liability under § 1962(d) is an agreement to participate in an endeavor which, if completed, would constitute a violation of the substantive statute." *Goren*, 156 F.3d at 732. Plaintiff's generalized, conclusory allegations that Defendants agreed "to limit the distribution of Acthar" and "inflate prices and maximize profits" do not satisfy *Iqbal* and, in any event, are not even RICO acts. (Compl. ¶¶ 175-76).

III. Plaintiff's ICFA Claim Fails for a Host of Reasons (Count VI).[5]

Plaintiff does not clearly identity the activities it contends violate ICFA, but appears to assert that the Acthar label is inaccurate. (Compl. ¶¶ 96, 120). This does not survive scrutiny.

A. Plaintiff is Not a "Person" Under ICFA and Lacks Standing.

For starters, Plaintiff is not a "person" within the meaning of ICFA and lacks standing to bring a claim. The Illinois Supreme Court has held that ICFA does not extend to body politics or municipal entities. *Board of Educ. Of City of Chicago v. A, C and S, Inc.*, 131 Ill.2d 428, 468 (1989) (finding that plaintiff-school districts lacked standing to pursue ICFA claims because municipal entities are not "persons"). Plaintiff, as a body politic and municipal corporation, lacks standing to sue under the ICFA, contrary to its bare assertion. (Compl. ¶¶ 184-185).

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[5] Since each federal claim over which the Court has original jurisdiction fails for the reasons above, the Court should decline to exercise supplemental jurisdiction over Plaintiff's alternatively-pleaded state law claims. (Compl. ¶¶ 13-16.); 28 U.S.C. § 1367(c); *Sidney Hillman*, 192 F. Supp. 3d at 997; *Groce v. Eli Lilly & Co.*, 193 F.3d 496, 501 (7th Cir. 1999).

B. Plaintiff's ICFA Claim is Impliedly Preempted by Federal Law.

Plaintiff's ICFA claim is also impliedly preempted by federal law and must be dismissed. The FDCA prohibits the distribution of any drug that is "misbranded" (*i.e.* sold with a false or misleading label). 21 U.S.C. § 352(a). As part of the FDA's approval process, manufacturers must submit proposed labeling to be used with the drug. *Id.* at § 355(b); 21 C.F.R. § 314.50(c)(2)(i). The FDA must approve the exact text in the proposed label. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b). A drug manufacturer may make changes to its label by (1) securing FDA approval for the change or (2) making a change pursuant to the "Changes Being Effected" ("CBE") regulations. 21 C.F.R. §§ 314.70(b); 314.70(c)(6)(iii); *see also In re Celexa and Lexapro Mktg. and Sales Practices Litig.*, 779 F.3d 34, 37 (1st Cir. 2015). The CBE regulations allow manufacturers of brand-name drugs to make changes to an FDA-approved label on the basis of "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii).

Plaintiff seeks to impose liability based upon the content of the FDA-approved Acthar label. If a drug manufacturer must obtain FDA approval to take action to comply with state law, the state law is preempted. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623-24 (2011). In the context of a labeling claim, the inquiry is whether the manufacturer could have corrected the label without FDA approval using the CBE regulation. *See e.g., Celexa*, 779 F.3d at 41 (consumer claim based on misleading label preempted where manufacturer could not have "independently" altered label); *PLIVA*, 564 U.S. at 623 (failure to warn claims against generic manufacturers preempted where manufacturers could not update label unilaterally under CBE regulations).

While Mallinckrodt contends the Acthar label is accurate in all respects, Plaintiff does not allege Mallinckrodt can unilaterally change the FDA-approved label without FDA involvement. Plaintiff admits the relevant ACTH amino acid sequence was discovered in 1972 and the FDA approved the Acthar label in 2010. (Compl. ¶¶ 36, 102-103). There is no "newly acquired

information" that would support a change under the CBE regulations. The claim is preempted.

C. Plaintiff's Claim Also Falls Within Section 10b(1)'s Safe Harbor Exemption.

Section 10b(1) of ICFA expressly excludes from liability "actions … specifically authorized by laws administered by any regulatory body or offices acting under statutory authority of this State or the United States." 815 ILCS 505/10b(1). Here, Plaintiff's claim falls squarely within 10b(1) because the labeling at issue was specifically authorized, and, in fact, approved, by the FDA under the authority of the FDCA. *Bober v. Glaxo Wellcome PLC,* 246 F.3d 934, 941 (7th Cir. 2001). In *Bober*, the Seventh Circuit, in applying the 10b(1) safe harbor to dismiss the plaintiff's ICFA claim against the manufacturer of Zantac, explained that because its statements regarding Zantac "f[ell] within the boundaries established by federal law," they were entitled to protection under Section 10b(1). *Id.* at 942-43; *see also Price v. Philip Morris, Inc.*, 219 Ill.2d 182, 262 (2005) (*citing Bober* and explaining that 10b(1) encompassed "statements that 'fall within the boundaries established by federal law' in a highly regulated industry, even if those statements may tend to be confusing or misleading").

Plaintiff cannot use ICFA to "impose higher disclosure requirements" than what was authorized, required, and approved by the FDA. *Bober.* 246 F.3d at 941. Mallinckrodt has an even stronger case for dismissal than the defendant in *Bober*, because there the alleged "misstatements" were not on the drug's label, but instead came from several other sources, including its website and a consumer hotline. *Id.* at 937.

D. In Any Event, Plaintiff Has Not Adequately Alleged an ICFA Claim.

In any event, Plaintiff has not plausibly alleged facts stating an ICFA claim. Plaintiff has not adequately alleged a single actionable misrepresentation or deceptive or unfair practice. Where, as here, a claim "sounds in fraud," Rule 9(b)'s heightened pleading standard applies, which "ordinarily requires describing the who, what, when, where, and how of the fraud."

Camastra v. Jos. A. Bank Clothiers, Inc., 761 F.3d 732, 736 (7th Cir. 2014).

In attempting to fashion a claim, Plaintiff misstates the FDA-approved Acthar label.[6] Plaintiff claims "Acthar's label states that it contains porcine ACTH (adrenocorticotropic hormone)." (Compl. ¶ 100). Not so. The label describes Acthar as "adrenocorticotropic hormone (ACTH)"; the label also indicates Acthar is a "repository corticotropin injection." Contrary to Plaintiff's claims, there is no representation about whether Acthar contains "porcine" or "deamidated porcine" ACTH. (Compl. Ex. D, pp. 1, 4; Ex. E, pp. 1, 12; *see* Compl. ¶ 117).[7]

Plaintiff also generally alleges Mallinckrodt made "representations concerning … the appropriateness of Acthar to treat their indicated conditions and the appropriateness of the prices charged for Acthar." (Compl. ¶ 191). Plaintiff wholly fails to identify the details of such representations, because none were made. Similarly insufficient is Plaintiff's naked contention that Acthar contains less corticotropin than is asserted on the label (which would be a matter for the FDA in any event[8]). Plaintiff actually asserts elsewhere in the Complaint that Mallinckrodt "never disclosed the active ingredient in the Acthar being sold, or the potency of such product." (Compl. ¶¶ 109, 112-14). And to the extent Plaintiff attempts to ground its ICFA claim on supposed and unidentified "unfair methods of competition" or "unfair or deceptive acts or practices," "charging an unconscionably high price generally is insufficient to establish a claim of unfairness." *Siegel v. Shell Oil Co.*, 656 F. Supp. 2d 825, 833 (N.D. Ill. 2009).

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[6] Plaintiff interchangeably uses the terms "Label" and "Package Insert." (Compl. ¶¶ 105, 109).

[7] Plaintiff also claims that because of a change in the "scientific understanding" of the structure of ACTH in 1972, the Acthar label – which was approved by the FDA in 2010 following its comprehensive review – is incorrect. (Compl. ¶¶ 102-106). Not so. In fact, Plaintiff's own allegations reveal that the "Description" section of the FDA-approved label diagraming the amino acid sequence at issue in Acthar is entirely accurate for adrenocorticotropic hormone – a.k.a. ACTH. (Compl. ¶¶ 103-105; Compl. Ex. D, p. 4; Ex. E, p. 12).

[8] *See* 21 U.S.C. § 337(a); 21 U.S.C. § 351.

Nor can Plaintiff establish proximate causation or actual damages, both of which are required elements of an ICFA claim. *Camastra*, 761 F.3d 739; (*See also* Section 2(A)(5), supra). Critically, Plaintiff cannot, and does not, allege that it relied upon the statements at issue in determining whether to reimburse claims for Acthar. *See DeBouse v. Bayer*, 235 Ill.2d 544, 555 (Ill. 2009) (holding that plaintiff could not establish proximate cause where she was not "actually deceived by a statement or omission"). Nor can or does Plaintiff allege that it, or anyone else, would have acted differently if Acthar's label was different in any respect. Plaintiff further cannot and does not allege Acthar was ineffective. Nor can Plaintiff show it sustained actual damages, since speculative and conclusory statements about possible lower prices in the market are insufficient to show an ICFA injury. *Camastra,* 761 F.3d at 739-40; *DeBouse*, 235 Ill.2d at 555 (rejecting "market theory" of causation).

IV. Plaintiff's Unjust Enrichment and Civil Conspiracy Claims Fail (Counts VII, VIII).

Plaintiff's unjust enrichment claim fails because there is no underlying tort or unlawful conduct. *Martis v. Grinnell Mut. Reinsurance Co.*, 388 Ill. App. 3d 1017, 1025 (3d Dist. 2009). In the absence of any deception, there can be no violation of "fundamental principles of justice, equity, and good conscience" and no unjust enrichment. *Bober*, 246 F.3d at 943; *Cleary v. Philip Morris, Inc.*, 656 F.3d 511, 517 (7th Cir. 2011).

Plaintiff's civil conspiracy claim fails for the same reasons its RICO conspiracy claim fails. *See, e.g., Bober*, 246 F.3d at 943. Plaintiff has not adequately alleged an underlying tort or underlying unlawful act that could support a conspiracy claim or the precise agreement between the parties. *Redelmann v. Claire Sprayway, Inc.,* 375 Ill. App. 3d 912, 923 (1st Dist. 2007). The mere characterization of a combination of acts as a conspiracy is insufficient. *Id.*

V. Statutes of Limitations.

In addition to the pleading deficiencies set out above, much of the alleged conduct

supporting each claim falls outside of the applicable limitations period for the respective Count. The supposedly wrongful conduct alleged in the complaint began in July 2007, almost ten years prior to the filing of the complaint. With respect to Plaintiff's antitrust claims under the Sherman Act, there is a four-year statute of limitations. 15 U.S.C. § 15b (2012). Similarly, RICO claims are subject to a four-year statute of limitations. *McCool v. Strata Oil Co.*, 972 F.2d 1452, 1463-64 (7th Cir. 1992). With respect to Plaintiff's state law claims, ICFA claims are subject to a three-year statute of limitations. 815 Ill. Comp. Stat. 505/10a(e) (2010). Unjust enrichment and civil conspiracy claims are both subject to a five-year statute of limitations. 735 Ill. Comp. Stat. 5/13-205 (2010).

Plaintiff alleges it paid for nine administrations of Acthar to two patients, but fails to plead any facts indicating when the reimbursements were supposedly made. (Compl. ¶ 12). To the extent Plaintiff's reimbursements for Acthar fall outside of each claim's respective limitations period, Plaintiff's claims are time-barred. Plaintiff has made no effort to plead fraudulent concealment or other possible grounds for equitable tolling of the limitations periods, nor is there a basis for such assertions. Plaintiff's failure to allege specific facts regarding its alleged Acthar reimbursements further demonstrates the insufficiency of its Complaint.

CONCLUSION

The Court should, respectfully, dismiss the Complaint with prejudice in its entirety.

Dated: August 22, 2017

Respectfully Submitted,

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CERTIFICATE OF LAWYER

The undersigned hereby certifies that on August 22, 2017, I electronically filed the foregoing instrument with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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